

From the  
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY  
(PCT Rule 43bis.1)

Date of mailing  
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference  
see form PCT/ISA/220

FOR FURTHER ACTION  
See paragraph 2 below

International application No.  
PCT/GB2005/050017

International filing date (day/month/year)  
16.02.2005

Priority date (day/month/year)  
18.02.2004

International Patent Classification (IPC) or both national classification and IPC  
A61L24/06, A61B5/04, A61L15/58, A61L26/00

Applicant  
MANTRA INTERNATIONAL LTD.

COPY

1. This opinion contains indications relating to the following items:

- Box No. I Basis of the opinion
- Box No. II Priority
- Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- Box No. IV Lack of unity of invention
- Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- Box No. VI Certain documents cited
- Box No. VII Certain defects in the international application
- Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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Box No. I Basis of the opinion

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1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.  
 This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material:  
 a sequence listing  
 table(s) related to the sequence listing
  - b. format of material:  
 in written format  
 in computer readable form
  - c. time of filing/furnishing:  
 contained in the international application as filed.  
 filed together with the international application in computer readable form.  
 furnished subsequently to this Authority for the purposes of search.
3.  In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

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Box No. II Priority

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1.  The validity of the priority claim has not been considered because the International Searching Authority does not have in its possession a copy of the earlier application whose priority has been claimed or, where required, a translation of that earlier application. This opinion has nevertheless been established on the assumption that the relevant date (Rules 43bis.1 and 64.1) is the claimed priority date.
2.  This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43bis.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.
3. Additional observations, if necessary:

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**Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or  
industrial applicability; citations and explanations supporting such statement**

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**1. Statement**

Novelty (N)                    Yes: Claims      1-32  
                                  No: Claims

Inventive step (IS)           Yes: Claims      1-32  
                                  No: Claims

Industrial applicability (IA)   Yes: Claims      1-32  
                                  No: Claims

**2. Citations and explanations**

**see separate sheet**

**Re Item V.**

**1 Reference is made to the following documents:**

D1 : US 2003/153964 A1  
D2 : WO 00/06214 A

**2 NOVELTY**

D1 discloses a bioadhesive composition that can contain conductivity imparting anionic group containing monomers for use as electrodes. The composition can comprise 1) alkoxy polyethylene glycol (meth)acrylates 2) a second monomer containing conductivity imparting anionic groups, e.g. Na-AMPS 3) a crosslinking agent, e.g. polyethylene glycol dimethacrylate 4) plasticiser, e.g. glycerol 2-20 wt% 5) water 6) photoinitiator, etc.(see D1, paragraphs 17-28,33,34; examples; claims). However, D1 does not disclose the range of amounts or specific ratios of ingredients, nor the selection of components as disclosed in independent claims 1,23,24,25,26,29,30,31,32.

D2 discloses hydrogel adhesives for skin electrodes made from a first monomer, e.g. Na-AMPS and a second monomer, e.g. K-SPA, preferably in a ratio 10:1 to 2:3. Comonomers can be present such as acrylic acid as well as glycerol, water and a photoinitiator (see D2, page 11, line 10-17; examples; claims). However, D2 does not disclose the range of amounts or specific ratios of ingredients, nor the selection of components as disclosed in independent claims 1,23,24,25,26,29,30,31,32.

Therefore, the subject-matter of claims 1-32 is novel in the sense of Article 33(2) PCT.

**3 INVENTIVE STEP**

The problem to be solved can be regarded as to provide improved conductive soft bioadhesive hydrogels in which the bioadhesive and electrical conductivity are not controlled by the water content of the hydrogel, but by the chemical composition of the formulation.

The **solution** is to provide a bioadhesive hydrogel comprising an aqueous mixture of two or more water-soluble monomers, i.e. an olefinically unsaturated sulfonic acid and an olefinically unsaturated carboxylic acid, an aqueous plasticiser, i.e. an alkoxy polyethylene glycol (meth)acrylate, crosslinking agent and water (cf. claims 1,23,24,25,26,29,30,31,32).

D1, which may be regarded as the **most relevant state of the art**, discloses a composition comprising 1) alkoxy polyethyleneglycol (meth)acrylates 2) a second monomer containing conductivity imparting anionic groups, e.g. Na-AMPs 3) a crosslinking agent, e.g. polyethylene glycol dimethacrylate 4) plasticiser, e.g. glycerol 2-20 wt% 5) water 6) photoinitiator, etc.(see D1, paragraphs 17-28,33,34; examples; claims). The difference between D1 and the present application is that D1 does not disclose the range of amounts or specific ratios of ingredients, nor the selection of components as disclosed in independent claims 1,23,24,25,26,29,30,31,32.

The **surprising technical effect** of the composition disclosed in the present application is that the electrodes have been found to stay on and continue to work for hours even in sweaty conditions and survive and retain its power of adhesion after even more than 100 uses in normal conditions.

It would not be obvious for a person skilled in the art from the teachings of D1 to arrive at the solution proposed in the subject-matter of independent claims 1,23,24,25,26,29,30,31,32 to solve the problem posed.

Therefore, the subject-matter of claims 1-32 involves an inventive step in the sense of Article 33(3) PCT.